

REMARKS

In the aforesaid Office Action, claims 1-3 and 9 were rejected under 35 USC § 102(b) as being anticipated by Sun et al. (U.S. Patent No. 5,728,748), claims 10 and 11 were rejected under 35 USC § 103(a) as being unpatentable over Sun et al. alone, claims 1-3, 9-11, 13-15, 24, 25, and 27-30 were rejected under 35 USC § 103(a) as being unpatentable over Chen et al. (U.S. Patent No. 5,849,846) in view of Sun et al., and claims 12, 31, and 32 were rejected under 35 USC § 103(a) as being unpatentable over Chen et al. in view of Sun et al. and further in view of Avellanet (U.S. Patent No. 5,733,496). Applicants note with appreciation the indication that claims 21-23 and 26 are allowed, and claims 4-8 and 16-20 would be allowable if rewritten in independent form including all limitations of the base and any intervening claims. Claims 1-3, 5, 7-12, 14-24 and 26-33 are pending (new claim 33 being added, and claims 4, 6, 13 and 25 being cancelled by this amendment).

The Examiner rejected claims 1-3, 9-11, 13-15, 24, 25, and 27-30 under 35 USC § 103(a) as being unpatentable over Chen et al. (U. S. Patent No. 5,849,846) in view of Sun et al., stating that Chen et al. teaches irradiating a medical device component with an electron beam so as to increase burst strength and pressure, and fatigue strength, and that Chen et al. is silent as to whether the e-beam radiation sterilizes the component; but Sun et al. teaches that e-beam radiation is effective in sterilizing polymeric materials, and one of ordinary skill in the art would have found it obvious to use the e-beam sterilization of Sun et al. to both improve the performance characteristics of the component and to

sterilize the component. The Examiner further states that Chen et al. does not disclose treating the component within a sealed, evacuated container, and Sun et al. teaches a method of sterilizing a medical implant wherein the implant is placed within an air-tight container, the container evacuated and then repressurized with an inert gas, and that as Sun et al. discloses removing oxygen is necessary to prevent oxidation of the implant, it would have been an obvious step in the method of Chen et al.

However, Chen et al. in view of Sun et al. does not disclose or suggest providing a balloon catheter having a balloon with a first rupture pressure, and applying an electron beam to the balloon catheter in an evacuated or inert gas-filled container, so that the electron-beamed balloon has a second rupture pressure equal to or not significantly less than the first rupture pressure, as required by the embodiment of Applicant's invention set forth in claim 14. Instead, Chen et al. discloses that irradiating the catheter balloon increases the burst pressure and fatigue strength of the balloon (see column 9, lines 20-25).

Moreover, because Chen et al. discloses that irradiation increases the burst pressure of the catheter balloon by toughening the balloon, there is no motivation to combine Chen et al. with the method of Sun et al. for avoiding irradiation-induced oxidative degradation of a polymeric material. The Examiner states that because Sun et al. discloses that removing oxygen from the environment of the implant is necessary to prevent oxidation of the implant, it would have been an obvious step in the method of Chen et al. However, Sun et al. discloses that irradiation without the method of Sun et al.

will result in oxidative degradation, whereas Chen et al. teaches that the irradiation toughens the balloon material (rather than oxidizing/degrading the balloon material).

The Examiner rejected claims 12, 31, and 32 under 35 USC § 103(a) as being unpatentable over Chen et al. in view of Sun et al. and further in view of Avellanet, stating that Chen et al. teaches the application of e-beam radiation to catheter balloons but does not teach balloons made of the instant materials, and that Avellanet teaches irradiating catheter balloons made of PEBA<sup>X</sup> and PTFE. However, Applicants have carefully reviewed Avellanet and can find no teaching or suggestion of irradiating catheter balloons or balloons formed of the instant materials. Rather, Avellanet appears to disclose irradiating a catheter shaft and not a balloon. Avellanet discloses increasing the stiffness of catheter tubing to increase the push and torque of the catheter (see Background section), which relate to catheter shafts and not balloons, and Avellanet makes no reference to a balloon or a balloon catheter.

The Examiner indicated that claim 6 would be allowable if rewritten in independent form including all limitations of the base and any intervening claims. Applicants have amended claim 1 to include the limitations of claim 6 and only some of the limitations of intervening claim 5, and none of the limitations of intervening claims 2 and 3.

The Examiner objected to claim 20 as being dependent on a rejected base claim. Applicants have added new claim 33 corresponding to claim 20 rewritten in independent form.

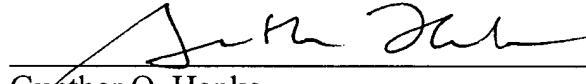
Applicants wish to bring to the attention of the Patent Office the reference listed on the attached PTO/SB/08B and request that it be considered by the Examiner. The Information Disclosure Statement is being submitted under 37 CFR § 1.97(c)(2), and therefore the fee, \$180.00, as set forth in CFR § 1.17(p) is enclosed.

In light of the above amendments and remarks, applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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